



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15CT]

Proposed Data Collections Submitted for
Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

- (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- (b) the accuracy of the agency's estimate of the burden of the proposed collection of information;
- (c) ways to enhance the

quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Sudden Death in the Young Registry - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Every year, infants, children and youth die suddenly and unexpectedly from previously undiagnosed conditions. Little is known about the risk factors leading to SDY, although underlying genetic conditions contribute in some cases. For example, the risk of SDY is known to be higher for infants and children with heart-related conditions or neurological conditions such as epilepsy. However, estimates of the annual incidence of Sudden Death in the Young (SDY) vary broadly due to differences in definitions, inconsistencies in classifying cause of death on death certificates, differing case ascertainment methodologies, and other factors.

To address this gap in knowledge, the Centers for Disease Control and Prevention (CDC), the National Heart, Lung and Blood Institute (NHLBI), and the National Institute for Neurological Disorders and Stroke (NINDS) are collaborating with selected states and partner organizations to create the Sudden Death in the Young Registry (SDYr). The SDYr will establish the first uniform reporting system for SDY based on shared standards for reviewing and classifying deaths involving infants and children < 19 years of age, and the systematic participation of individuals with expertise in key medical specialties. Up to 15 state health departments will receive funding from CDC to report standardized information to a central database for compilation

and analysis. In addition, each awardee will establish an advanced clinical review team consisting of a forensic pathologist, neurologist, epileptologist, and pediatric cardiologist to supplement its existing Child Death Review (CDR) process. Specialized medical expertise is essential to the accurate determination of cause of death.

The SDYr will build on ongoing collaborations involving state-based child death review teams, CDC, the National Institutes of Health (NIH), the Health Resources and Services Administration (HRSA), and the National Center for the Review and Prevention of Child Deaths (NCRPCD) at the Michigan Public Health Institute (MPHI). The MPHI-NCRPCD is a non-profit organization dedicated to preventing child deaths and serious injuries. The MPHI-NCRPCD provides technical assistance and training on death scene investigation, and prevention strategies, to partner organizations including state and local governments. The MPHI-NCRPCD also supports a Web-based National Child Death Review Case Reporting System that states can use on a voluntary basis to manage their state-specific CDR data. The system is currently used by 43 states free of charge. Due to variability in case definitions and reporting procedures, the system does not produce national estimates, but serves as a vital repository of information to facilitate state-based surveillance and public health activities.

Utilizing MPHI-NCRPCD Case Reporting System (CRS) infrastructure, MPHI and CDC have previously collaborated with nine states to strengthen case definition and surveillance for sudden unexpected infant death (SUID) involving infants < one year of age. The SDYr will build on this collaboration by increasing the number of participating states, systematically engaging key medical experts in the review of deaths of children < 19 years of age, and requiring the collection and reporting of standardized data elements. States participating in the SDYr will report information through a special module called the NCRPCD-CRS-SDY Module. This information collection procedure was selected due to its familiarity to the majority of states, MPHI's successful collaborations with multiple partners, and shared interest in developing and promulgating best practices for the identification, classification, and prevention of SDY.

De-identified information collected through the SDYr will be used to generate estimates of the prevalence of SDY due to cardiac and neurologic conditions; to elucidate risk factors; and to develop evidence-based prevention strategies for SDY. The SDYr will also create the infrastructure for future expanded research. CDC is authorized to collect this information by Section 241 of the Public Health Service Act [42 USC 241].

CDC estimates that the participating states will collect data on approximately 1,000 SDY cases per year (20-150 per

state, with an average of 67 per state). No information will be collected directly from family members of the deceased. CDC estimates that each specialist on the advanced clinical review team will devote 15 minutes to the review and completion of the autopsy check list and other records associated with each death reported through the SDYr. For participating state health departments, the estimated burden for entering each case into the case reporting system is 30 minutes.

OMB approval is requested for three years. Reporting is required for cooperative agreement awardees. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State Health Department	NCRPCD-CRS-SDY Module	15	67	30/60	503
Pediatric Cardiologist	NCRPCD-CRS-SDY Module	15	67	15/60	251
Epileptologist	NCRPCD-CRS-SDY Module	15	67	15/60	251
Neurologist	NCRPCD-CRS-SDY Module	15	67	15/60	251
Forensic Pathologist	NCRPCD-CRS-SDY Module	15	67	15/60	251
Total					1,507

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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